

4400 Health Systems Protection

4405 Free Standing Surgical Centers

1.0 Definitions

“Division” means the Delaware Division of Public Health.

“Free Standing Surgical Center” (hereafter referred to as FSSC) means a facility which operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization. The term does not include:

- a facility that is licensed as part of a hospital, or;
- a facility that provides services and/or accommodations for patients who stay over-night, or;
- a facility which is used as an office or clinic for the private practice of a physician, podiatrist or dentist except when:
 - it holds itself out to the public or other health care providers as an FSSC or similar facility, or;
 - it is operated or used by a person or entity different than the physician(s), or;
 - patients are charged a fee for use of the facility in addition to the physician's professional services.

“Person” means sole proprietor, partnership, unincorporated association, corporation or any state, county, or local governmental unit.

2.0 General Terms, Conditions and Requirements

2.1 Chief Executive Officer

2.1.1 Responsibility: The chief executive officer shall be the official representative of the governing body and the chief executive officer of the surgical center. The chief executive officer shall be delegated responsibility and authority in writing by the governing body for the management of the surgical center and shall provide liaison among the governing body, provider staff and other departments of the surgical center.

2.1.2 Duties: The chief executive officer shall be responsible for the development of surgical center policies and procedures for employee and provider staff use. All policies and procedures shall be reviewed and/or updated as necessary but at least annually.

2.2 Governing Body

2.2.1 Responsibility: The Governing Body shall provide facilities, personnel, and services necessary for the welfare and safety of the patients.

2.2.2 Duties: The Governing Body shall:

- 2.2.2.1 adopt by-laws in accordance with legal requirements;
- 2.2.2.2 meet at least annually and maintain accurate records of such meetings;
- 2.2.2.3 appoint committees consistent with the needs of the surgical center;
- 2.2.2.4 make appointments and delineations of clinical and surgical privileges of practitioners based upon the standard of granting of privileges within the community, including surrounding providers of surgical services;
- 2.2.2.5 establish a formal means of liaison with the provider staff;
- 2.2.2.6 approve by-laws, rules and regulations of the provider staff or physicians with surgical privileges;
- 2.2.2.7 adopt appropriate policies on admissions, surgical procedures, and the timely completion of medical records;
- 2.2.2.8 conduct with the active participation of the provider staff, an ongoing, comprehensive self-assessment of the quality of care provided, including the medical necessity of procedures performed, the appropriateness of utilization. This information shall provide a basis for the revision of facility policies and the granting or continuation of clinical privileges;

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- 2.2.2.9 require that the facility's Quality Assurance Program ensure the adequate investigation, control and prevention of infectious diseases. All reportable communicable diseases are to be reported according to established rules and regulations of the Department of Health and Social Services;
- 2.2.2.10 develop admission policies and procedures in writing with appropriate guidelines by the provider staff and adopted by the Governing Body.
- 2.3 Attending Staff
 - 2.3.1 Physician - an individual who has received a Doctor of Medicine or Doctor of Osteopathy degree and is currently fully licensed to practice medicine in the State of Delaware.
 - 2.3.2 Anesthesiologists
 - 2.3.2.1 Physician anesthetists - an individual who is a physician certified by the American Board of Anesthesiology or who has training and experience in the field of anesthesiology, substantially equivalent to that required for such certification.
 - 2.3.2.2 Nurse or dentist anesthetists - licensed nurse or dentist who is able to provide general anesthesia. Their performance shall be under the overall direction of director of anesthesia services or his/her qualified anesthetist designee; otherwise, their performance shall be under the overall direction of the surgeon or obstetrician responsible for the patient's care.
 - 2.3.3 Dentist - an individual who is a graduate of a recognized school of Dentistry licensed to practice in the State of Delaware.
 - 2.3.4 Podiatrist - an individual who is a graduate of a recognized school of Podiatry licensed to practice in the State of Delaware.
 - 2.3.5 Registered Nurse means a graduate of an approved school of nursing and who is licensed to practice in the State of Delaware.
 - 2.3.6 Emergency Personnel - licensed medical staff and licensed registered nurse staff who are qualified by relevant training, experience and current competence in emergency care. When emergency medical technicians or other allied health personnel are used, their duties and responsibilities are to the physician(s) and nurse(s) providing care in the emergency situations.
 - 2.3.7 Ancillary Staff - auxiliary person(s) in the facility at all times to provide total care for patients. Workers are assigned clearly defined duties for which they are trained.
- 2.4 Ownership - The ownership and control of the facility and the property on which the FSSC is located shall be disclosed to the Department of Health and Social Services. Proof of this ownership shall be available in the facility. Any change in ownership shall be reported to Office of Health Facilities Licensing and Certification in writing immediately prior to or after the change.
- 2.5 All required records maintained by FSSC shall be open to inspection by the authorized representative of the Department of Health and Social Services.
- 2.6 Hours of services for the FSSC shall be conspicuously posted.

3.0 Licensing Requirements

- 3.1 The term "free standing surgical center" shall not be used as a part of the name of any facility or description of services in the State unless it has been so classified by the Department of Health and Social Services.
- 3.2 License:
 - 3.2.1 a license shall be effective for a twelve (12) month period and may be issued for that period only if the FSSC is in full compliance with these regulations.
 - 3.2.2 a provisional license may be granted by the Department of Health and Social Services for a period not exceeding three (3) months when the FSSC is in compliance with most but not all of these regulations and has demonstrated the ability and willingness to comply within the three (3) month period. Additional provisional licenses may be granted provided a good faith effort is being made to meet regulatory compliance.
 - 3.2.3 a license is not transferable from person to person nor from one location to another.

- 3.2.4 the license shall be conspicuously posted.
- 3.2.5 all applications for renewal of licenses shall be filed with the Division at least thirty (30) days prior to expiration.

4.0 Medical Records

- 4.1 Facilities: The center shall provide sufficient space and equipment for the processing and the safe storage of records.
- 4.2 Personnel: A person knowledgeable and trained in the management of Medical Records shall be responsible for the proper administration and functioning of the medical records section.
- 4.3 Security: Medical records shall be protected from loss, damage and unauthorized use.
- 4.4 Preservation: With the exception of medical records of minors (individuals under the age of 18 years), medical records shall be preserved as original records or on microfilm for no less than five (5) years after the most recent patient care usage, after which time records may be destroyed at the discretion of the facility.
 - 4.4.1 Medical records of minors shall be preserved for the period of minority plus five (.5) years (i.e., 23 years) or as stipulated by State law.
 - 4.4.2 Facilities shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.
 - 4.4.3 The sole responsibility for the proper destruction of all medical records shall be in the facility and destroyed in accordance with their administrative policy.
- 4.5 Content: The medical records shall contain sufficient accurate information to justify the diagnosis and warrant the treatment and end results including, but not limited to:
 - 4.5.1 complete patient identification and a unique identification number;
 - 4.5.2 admission and discharge dates;
 - 4.5.3 chief complaint and admission diagnosis;
 - 4.5.4 medical history and physical examination completed prior to surgery;
 - 4.5.5 diagnostic tests, laboratory and x-ray reports when appropriate;
 - 4.5.6 physician progress notes if appropriate;
 - 4.5.7 properly executed informed consent;
 - 4.5.8 a pre-anesthesia examination by a physician prior to surgery, a proper anesthesia record and a post-anesthesia follow up and any allergic and abnormal drug reactions;
 - 4.5.9 a pre-op diagnosis and nursing and other ancillary care personnel notes are required;
 - 4.5.10 a completed detailed description of operative procedures, findings and post-operative diagnosis recorded and signed by the attending surgeon;
 - 4.5.11 a pathology report of tissue removed during surgery in accordance with facility policies;
 - 4.5.12 all medication and treatment orders in writing and signed by the prescribing physician. Telephone and verbal orders are designated as such, signed and dated by a legally designated person, and countersigned by the prescribing physician within 72 hours;
 - 4.5.13 patient's condition on discharge, final diagnosis, and instructions given patient for follow-up care.
- 4.6 Other records: The facility shall maintain:
 - 4.6.1 a register of all operations performed (entered daily);
 - 4.6.2 statistical information concerning all admissions, discharges, deaths and other information such as blood usage, surgery complications, etc., required for the effective administration of the facility;
 - 4.6.3 master patient index file.
- 4.7 Nursing records: Standard nursing practice and procedure shall be followed in the recording of medications and treatments, including operative and post-operative notes. Nursing notes shall include notation of the instructions given patients pre-operatively and at the time of discharge. All recordings shall be in ink, and properly signed including name and identifying title.
- 4.8 Entries: All orders for diagnostic procedures, treatments and medications shall be signed by the physician submitting them and entered in the medical record in ink or in type.

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Authentication may be by written signature, identifiable initials or computer key. The use of rubber stamp signatures is acceptable under the following strict conditions:

- 4.8.1 The physician whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it and may not be used for controlled substances;
- 4.8.2 The physician places in the administrative office of the facility a signed statement to the effect that he/she is the only one who has the stamp and is the only one who will use it.

5.0 Personnel

- 5.1 Recruitment: The recruitment and employment of personnel shall be made without regard to sex, race, creed, handicap or national origin as long as qualifications are commensurate with anticipated job responsibilities.
- 5.2 Policies: There shall be appropriate written personnel policies, rules and regulations governing the conditions of employment, the management of employees and the types of functions to be performed, i.e., job descriptions, health records, evaluation of employee's work performance.
- 5.3 Orientation: The purpose and objectives of the surgical center shall be explained to all personnel as part of an overall orientation program which is documented in the individual employee record.
- 5.4 Staffing:
 - 5.4.1 A staff of persons sufficient in number and adequately trained to meet requirements for care shall be employed.
 - 5.4.2 In addition to staff engaged in direct care and treatment of patients, there must be sufficient personnel or contractual services to provide basic services such as laundry, housekeeping and plant maintenance.
 - 5.4.3 Routine inservice training shall be given and documented in the individual employee record.
 - 5.4.4 Current state licensure and/or registration number and date of expiration for all licensed personnel shall be maintained in the individual employee record.
- 5.5 Employment: No employee shall be less than eighteen years of age.

6.0 Medical Staff Services

- 6.1 All persons admitted to the FSSC shall be under the care of a licensed physician in the State of Delaware.
- 6.2 The FSSC shall arrange for one (1) or more licensed physicians to be on premises during all hours of surgical services.
- 6.3 The FSSC shall arrange for one (1) or more licensed physicians to be called in an emergency and shall be immediately available either in person or by electronic devices on a 24 hour basis.
- 6.4 A medical director shall be appointed and shall be responsible for the direction, provision and quality of medical care.
- 6.5 Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. Each member must be licensed and approved by the Delaware Board of Medical Practice.
- 6.6 Medical staff participate in the development and maintenance of a patient care evaluation system (quality assurance) including peer review and audit.
- 6.7 Medical staff must develop and implement written medical policies, including medical staff bylaws or their equivalent.
- 6.8 Medical practitioner shall be required to have a residence within the defined primary and/or secondary service population of the FSSC.

7.0 Nursing Services

- 7.1 Nursing Administration: The facility shall have an organized nursing department under the supervision of a Director of Nursing (or its equivalent) who is currently licensed by the State of Delaware as a professional registered nurse and who has responsibility and accountability for all nursing services.
- 7.2 The Director of Nursing (or its equivalent) shall be responsible for:
 - 7.2.1 delivery of appropriate nursing services to patients;
 - 7.2.2 development and maintenance of appropriate nursing service objectives, standards of nursing practice, nursing policy and procedure manuals and written job descriptions for all levels of nursing personnel;
 - 7.2.3 coordination of nursing services with other patient services;
 - 7.2.4 establishment of a means of adequately assessing and planning the nursing needs of patients and staffing to meet those needs;
 - 7.2.5 staff development including education which includes provisions for CPR certification or review.
- 7.3 Nursing Personnel: There shall be sufficient licensed and auxiliary nursing personnel on duty to meet the total nursing needs of patients:
 - 7.3.1 At least one registered nurse shall be in the facility at all times when a patient is in the facility;
 - 7.3.2. Nursing personnel shall be assigned duties consistent with their education and experience.
- 7.4 Medications and treatments: Medications and treatments shall be administered in accordance with all applicable laws and acceptable standards of practice.
- 7.5 Staff Meetings: Meetings of the nursing staff shall be held regularly to discuss, review and evaluate nursing care. Written minutes of these meetings shall be maintained and distributed to staff.
- 7.6 Inservice Education: All nursing personnel shall receive inservice education at least semi-annually which shall include, but not be limited to, infection control, fire and safety procedures.
- 7.7 Evaluations: There shall be an adequate plan of continuous evaluation of nursing care. The Director of Nursing shall periodically evaluate the adequacy of the facility to meet the nursing needs of its patients and shall participate in planning for needed improvements or revisions of facilities and services.
- 7.8 Circulating Nurse: A registered nurse, qualified by education and experience in operating room nursing, shall be present as a circulating nurse in each operating room during operative procedures.

8.0 Infection Control

- 8.1 Prevention and Control Services
 - 8.1.1 The facility shall establish and implement an infection prevention and control program. The chief executive officer shall ensure the development and implementation of the program.
 - 8.1.2 The facility shall establish and implement written policies and procedures regarding infection prevention and control, for patients and employees including, but not limited to the following:
 - 8.1.3 A system for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility and maintaining records for all patients or personnel having these infections, diseases or conditions;
 - 8.1.4 Reportable diseases shall be reported to the Director of the Division of Public Health;
 - 8.1.5 Care of patients with communicable diseases;
 - 8.1.6 Policies and procedures for exclusion from work and authorization to return to work for personnel with communicable diseases;
 - 8.1.7 Surveillance techniques to minimize sources and transmission of infection;

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- 8.1.8 Sterilization, disinfection and cleaning practices and techniques used in the facility including, but not limited to the following:
- 8.1.8.1 Care of utensils, instruments, solutions, dressings, articles and surfaces;
 - 8.1.8.2 Selection, storage, use and disposition of disposable and non-disposable patient care items;
 - 8.1.8.3 Methods to ensure that sterilized materials are packaged and labeled to maintain sterility and to permit identification of expiration dates;
 - 8.1.8.4 Procedures for care of equipment and other devices that provide a portal of entry for pathogenic micro-organisms;
 - 8.1.8.5 Techniques to be used during each patient contact, including handwashing before and after caring for a patient;
 - 8.1.8.6 Criteria and procedures for isolation of patients;
- 8.1.9 Each service in the facility shall develop written infection control policies and procedures for that service.
- 8.1.10 All personnel shall receive orientation at the time of employment and continuing inservice education regarding the infection prevention and control program.
- 8.1.11 The chief executive officer shall evaluate written reports of State and local inspections, including results of cultures taken of food, equipment and personnel, and shall take the necessary corrective action.
- 8.1.12 Facilities providing surgical services in an operating room and recovery area shall establish and implement policies and procedures regarding infection prevention and control, including but not limited to the following:
- Use of aseptic technique and scrub procedures;
 - Gowning and operating room attire;
 - Traffic control;
 - Cleaning of the operating room after each procedure and care of operating room equipment and anesthesia equipment.

8.2 Infectious Disease and Waste Removal

- 8.2.1 The facility shall establish and implement policies and procedures for the collection, storage, handling and disposition of all pathological and infectious wastes within the facility, and for the collection, storage, handling and disposition of all pathological and infectious wastes to be removed from the facility, including, but not limited to the following:
- 8.2.2 Needles and syringes shall be destroyed or disposed of in a safe and proper manner.
- 8.2.3 Needles and syringes and other solid, sharp, or rigid items shall be placed in a puncture resistant container and incinerated or compacted prior to disposal.
- 8.2.4 Non-rigid items, such as blood tubing and disposable equipment and supplies, shall be incinerated or placed in double, heavy duty, impervious plastic bags and disposed.
- 8.2.5 Fecal matter and liquid waste, such as blood and blood products, shall be flushed into the sewerage system.
- 8.2.6 All pathology specimens and waste, including gross and microscopic tissue removed surgically or by any other procedure, shall be incinerated.
- 8.2.7 Solid waste from the laboratory shall be incinerated or autoclaved prior to disposal.
- 8.2.8 Liquid waste from the laboratory shall be autoclaved prior to disposal into the sewerage system.
- 8.2.9 All tissue, including gross and microscopic tissue, removed surgically or by any other procedure shall be incinerated or interred.
- 8.2.10 Collection, storage, handling and disposition procedures of all pathological and infectious wastes within the facility shall meet the requirements of all state and federal codes.

9.0 Hospitalization

The FSSC must have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the FSSC. The FSSC

must have a written transfer agreement with such a hospital or all physicians performing surgery in the FSSC must have admitting privileges at such a hospital.

10.0 Administration of Anesthesia

- 10.1 The anesthesia services must be under the direction of a Board Certified or Board eligible anesthesiologist if general anesthesia is to be used or anesthesia other than local procedures.
- 10.2 In cases where other than local anesthesia is employed the anesthetic must be administered by only:
 - 10.2.1 A qualified anesthesiologist or
 - 10.2.2 A physician qualified to administer anesthesia or a certified nurse anesthetist. In those cases where a non-physician administers the anesthesia, the anesthetist must be under the supervision of the operating physician.

11.0 Pharmaceutical Services

- 11.1 Medications must be purchased, stored, administered and dispensed in compliance with applicable State and Federal Statutes and Regulations. Those requirements include, but are not limited to the following:
 - 11.1.1 Standing orders shall be written and administered in compliance with the regulations of the Board of Medical Practice.
 - 11.1.2 Verbal orders must be countersigned by the prescriber within 72 hours of receipt.
 - 11.1.3 A policy and procedure manual must be established and approved by the Governing Board:
 - 11.1.3.1 It shall be reviewed annually.
 - 11.1.3.2 Any additions or deletions should show an effective date.
 - 11.1.3.3 It shall contain automatic stop orders; labeling requirements; discontinued medication policy; drug storage policy; charting policy; medication error policy; drug recall policy; prescriber medication order procedure; outdated medication procedures.
 - 11.1.4 Rubber stamp signatures are not acceptable for controlled substances orders.
 - 11.1.5 Medication must be stored according to the latest USP/NF standards.
 - 11.1.5.1 Room temperatures 59° to 86° F (15° to 30° C); refrigerator 36° to 46°F (2.2° to 7.8° C).
 - 11.1.6 Medications shall be properly secured in locked areas only accessible to authorized persons:
 - 11.1.6.1 Schedule II medications shall be under double lock.
 - 11.1.7 Internal medications shall be stored separately from external medications.
 - 11.1.8 All medications shall be accurately and plainly labeled:
 - 11.1.8.1 Dispensed medications shall be labeled in compliance with 24 Del.C. §2563.
 - 11.1.8.2 Prepacks must be labeled in compliance with Board of Pharmacy Regulation B.
 - 11.1.9 All medications on site or dispensed must be in packaging which complies with the latest edition of USP/NF.
 - 11.1.10 Medications not in sealed unit dose packaging shall not be returned to the container for reuse.
 - 11.1.11 Medications discontinued must be properly documented on the patient's chart or other applicable record.
 - 11.1.11.1 Controlled substance documentation should contain two signatures.
 - 11.1.12 Only licensed physicians or nurses may administer medications.
 - 11.1.13 Only a physician or pharmacist may dispense medications.
 - 11.1.13.1 Nurses may assist the physician with dispensing provided the physician directly supervises that person (24 Del.C. §2521).

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- 11.1.14 Stock supplies of controlled drugs can only be destroyed via procedures established by ONDD or DEA.
- 11.1.15 Syringes must be stored and destroyed in compliance with 16 **Del.C.** §4757, State CSA Regulation 5.
- 11.1.16 An emergency kit with quantities and types of medication determined by the medical staff shall be on the premises:
 - 11.1.16.1 A copy will be filed with the Board of Pharmacy.
 - 11.1.16.2 Written notification of any additions or deletions must be sent to the Division within 10 days after the change becomes effective.
 - 11.1.16.3 A log must be maintained on the premises for a period of 2 years from the last entry. It must show the date of administration or dispensing, the time, the name, strength and quantity of the drug involved, the name of the patient and the initials of the person removing the medication. The same information concerning the receipt of medication must be documented.
- 11.1.17 The site must be properly registered under the State and Federal Controlled Substances Acts.

12.0 Surgical Services

- 12.1 Location: The operating room (s) and accessory areas shall be located so that in and out traffic is properly controlled.
- 12.2 Patient Preparation Area: A patient preparation area with adjacent toilet facilities must be provided near the surgical suite. This area must provide for privacy and comfort of the patients and for storage of patient's clothing.
- 12.3 Surgical Privileges Roster: An up-to-date roster of staff providers specifying the approved surgical privileges of each shall be kept on file and available to nursing staff.
- 12.4 Doorways and Corridors: The minimum width of doors for patients and equipment shall be 3'0". Doors to accommodate stretchers must be at least 3'8" wide. The minimum width of corridors serving surgery suites and recovery and patient preparation areas from these areas must be at least 8 feet.
- 12.5 Operating Room(s): Each room shall be large enough to accommodate equipment and personnel for surgical procedures to be performed. If general anesthesia is to be administered during the surgery, the room shall contain a minimum of 350 square feet and; adequate provisions shall be made for an emergency communication system connecting the surgical suite.
- 12.6 Recovery Room(s): The FSSC must have a separate recovery room.
- 12.7 Waiting Area: Public waiting area with toilet facilities, drinking fountains and telephones shall be provided.
- 12.8 Structural Features: All other structural features must be in compliance with construction guidelines as defined in Section 15.0 of these regulations.
- 12.9 Ancillary Areas: In addition to operating room(s), the following physically separated areas shall be provided within the suite and shall be separated by doors and/or walls:
 - 12.9.1 scrub area
 - 12.9.2 cleanup room
 - 12.9.3 instrument and supply storage
 - 12.9.4 janitor's facilities
- 12.10 Scrub Area: The scrub area shall be adjacent to the operating room to permit immediate access to the room after scrubbing. Scrub sink(s) with knee or foot controls shall be installed in the scrub area.
- 12.11 Clean-Up Facilities: Clean and soiled utility rooms shall be arranged and provided with equipment necessary for proper patient care and for the processing of soiled equipment, including a pressurized steam sterilizer, or equivalent, storage cabinets and work counters with sinks.

- 12.12 Staff Dressing Room: Rooms shall be provided for both men and women, each containing a toilet, handsink and provisions for storage of clothing.
- 12.13 Oxygen: A supply of oxygen shall be available and stored in accordance with rules and regulations of State Fire Prevention Commission.
- 12.14 Equipment: The following minimum equipment must be available in the surgical suite:
 - 12.14.1 cardiac monitor
 - 12.14.2 resuscitator
 - 12.14.3 defibrillator
 - 12.14.4 aspirator
 - 12.14.5 thoracotomy set
 - 12.14.6 tracheotomy set and equipment for airway maintenance
 - 12.14.7 suction equipment
 - 12.14.8 emergency call system
 - 12.14.9 ventilatory assistance equipment including airways, manual breathing bag and ventilator.

13.0 Laboratory and Radiologic Services

- 13.1 The FSSC shall have provisions for the required laboratory, x-ray and other diagnostic services.
- 13.2 Whether these services are provided on-site or by contract, the provision of the services must meet state codes as set forth by the Department of Health and Social Services and Authority on Radiation Protection.
- 13.3 Prior to construction, the floor plans and equipment arrangements of all new installations or modifications of existing installations, utilizing x-rays for diagnostic purposes shall be sent to the Radiation Control Office, P.O. Box 637, Dover, DE 19903, for review and approval [DRCR F.3(b)J]. The required information is denoted in Appendices A and B of the Delaware Radiation Control Regulations (DRCR).
- 13.4 Each person having a radiation machine facility shall apply for registration of such facility with the Radiation Control Office (see above) prior to the operation of a radiation machine. Application for registration shall be completed on forms furnished by the Radiation Control Office and shall contain all the information required by the form and accompanying instructions [DRCR B.4 (b)].

14.0 Fire Safety

- 14.1 Fire safety in FSSC's shall comply with adopted rules and regulations of the State Fire Prevention Commission. Enforcement of the Fire Regulations is the responsibility of the State Fire Prevention Commission. All applications for license or renewal of license must include with the application, a letter certifying compliance by the Fire Marshal having jurisdiction. Notification of non-compliance with Rules and Regulations of State Fire Prevention Commission shall be grounds for revocation of license.
- 14.2 Staff shall be made familiar, by regular fire drills at least quarterly, with emergency and evacuation plans. Written records shall be kept of such drills.
- 14.3 Emergency plans shall be posted in a conspicuous place on all floors.
- 14.4 Smoking regulations are adopted on control smoking, and include the posting of "No Smoking" signs in any room, ward, or compartment where flammable liquids, combustible gases, or oxygen are used or stored, and in any other hazardous location.
- 14.5 Flammable and Explosive Gases
 - 14.5.1 A separate room shall be provided for the storage of flammable gases in accordance with the requirements of NFPA Life Safety Code 99 Standards (Health Care Facilities Standards) if such gases are used.

14.5.2 Space for reserve storage of nitrous oxide and oxygen cylinders shall be provided and constructed of one hour fire resistive construction and in accordance with NFPA 56 Standards.

14.6 Furnishing and Decorations

14.6.1 No furnishings, decorations or other objects are placed as to obstruct exits or visibility of exits.

14.6.2 No furnishings or decorations of an explosive or highly flammable character are used. Furnishings and decorations are in accordance with NFPA Standards.

14.6.3 All combustible curtains including cubicle curtains are rendered and maintained flame-retardant.

15.0 Plant, Equipment and Physical Environment

15.1 Building:

15.1.1 All NEW construction, extensive remodeling or conversions shall comply with the standards set forth under the Outpatient Surgical Facility section of the current or subsequent editions of "Guidelines for Construction and Equipment of Hospital and Medical Facilities", a publication of the U.S. Department of Health and Human Services.

15.1.2 One set of plans is to be submitted to Office of Health Facilities Licensing and Certification for their review and approval prior to construction or remodeling.

15.2 Plumbing:

15.2.1 The plumbing shall meet the requirements of all municipal, state or county codes. Where there are no local codes, provisions of the Department of Health and Social Services regulations governing a detailed plumbing code shall prevail.

15.3 Heating:

15.3.1 The heating equipment for all sections of the FSSC shall be adequate, safe, protected and easily controlled. It shall be capable of maintaining the temperature in each room at a minimum of 72°F (21°C). Portable heating equipment is strictly prohibited in a FSSC.

15.4 Lighting:

15.4.1 Each room must be adequately lighted at all times for maximum safety, comfort, sanitation and efficiency of operation. This includes hallways, stairways, storerooms, bathrooms, dressing rooms, operating rooms and recovery rooms.

15.4.2 All entrance and/or egress doors must be properly lighted at all times during operation hours of the FSSC.

15.5 Exhaust:

15.1.1 At least two (2) exhaust outlets shall be provided in each operating room, not less than four (4) inches above the floor.

15.1.2 All rooms shall be ventilated to help prevent condensation, mold growth and noxious odors.

15.6 Electrical:

15.6.1 All electrical requirements shall be in compliance with all municipal or county codes.

15.7 Mechanical Equipment:

15.7.1 Mechanical equipment shall be kept in working order at all times.

15.8 Housekeeping:

15.8.1 Facility shall establish and implement a written work plan for housekeeping operations, with categorization of cleaning assignments as daily, weekly, monthly or annually within each area of FSSC.

15.9 Pest Control:

15.9.1 The building shall be so constructed and maintained to prevent the entrance or existence of rodents and insects at all times.

15.10 Furnishings:

15.10.1 All furnishings shall be clean and in good repair. All equipment and materials necessary for cleaning, disinfecting and sterilizing shall be provided.

15.11 Thermometers:

15.11.1 Thermometers shall be maintained in refrigerators, freezers and storerooms used for perishables and other items subject to deterioration.

15.12 Emergency Power:

15.12.1 An emergency generator shall be provided as an emergency power source for lighting and equipment of operating rooms, recovery rooms and corridors in accordance with NFPA Standards.

15.13 Laundry and Linens:

15.13.1 Written provisions shall be made for the proper handling of linens and washable goods.

15.13.2 Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries for FSSC's shall meet all local and state regulations.

15.13.3 Soiled Processing:

15.13.3.1 If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.

15.13.3.2 Soiled Linen Transportation: Soiled linen shall be enclosed in an impervious bag and removed from surgery units after each procedure.

15.13.3.3 Soiled Linen Carts: Carts, if used to transport soiled linen, shall be constructed of impervious materials, cleaned and disinfected after each use.

15.13.3.4 Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry.

15.13.4 Processing: The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.

15.13.5 Washing Temperatures: The temperatures of water during water process shall be controlled to provide a minimum temperature of 165° (74°C) for at least 25 minutes.

15.13.6 Clean Processing:

15.13.6.1 The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.

15.13.6.1 Clean Linen Storage Room: Adequate provisions shall be made for storage of clean linen.

15.13.6.2 Procedures: Adequate procedures for the handling of all laundry and for the positive identification and proper packaging and storage of sterile linens must be developed and followed.

15.14 Incineration:

15.14.1 Agreement: If there is no pathological incinerator on the premises, the facility must have an agreement with another facility that has an approved pathological incinerator for the proper disposal of pathological waste.

15.14.2 Incinerator for Pathological Waste: Any pathological waste incinerator must meet the appropriate Clean Air Act of the state.

15.14.3 Refuse Incinerators: Refuse incinerators are prohibited.

16.0 Patient Rights

16.1 Facility shall support and protect the fundamental human, civil, constitutional and statutory rights of each patient by establishing written policies regarding the rights of patients. These policies and procedures shall be available to the patients and the general public.

16.2 Each patient shall have impartial access to treatment, regardless of race, religion, sex, ethnic background, age or handicap.

16.3 Each patient's personal dignity shall be recognized and respected in the provision of all case and treatment.

16.4 Each patient shall receive individualized treatment with the provision of adequate and humane services regardless of the source(s) of financial support.

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- 16.5 Each patient is assured confidential treatment of his or her medical/health record and shall approve or refuse its release to any individual outside the facility, except as required by law or third party payment contract.

17.0 Discharge

All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

18.0 Severability

Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be thereby affected.